

**REMARKS**

Claims 1-41 have been subjected to restriction for prosecution on the merits under 35 U.S.C. §§121 and 372. Claims 1-4, 6-9, 12-13, 15-16, 19, 26, and 34 are pending after entry of the instant paper. Claims 5, 10-11, 14, 17-25, 27-33, and 35-41 have been cancelled without prejudice. Applicants reserve the right to pursue the subject matter of the withdrawn or cancelled claims in a continuing application.

Claim 1 has been amended by adding the types of formats for administering the corrective gene, *i.e.*, naked DNA or liposome subsumption. Support for the claimed formats may be found throughout the specification, for example, at the top of page 14.

Claims 1, 8, have been amended Support for the clarification of the gene may be found throughout the specification, for example, at pages 2, 7, 9, 12, and 13, where the gene used in gene therapy corrects the deficient gene that is responsible for genetic disease. For example, Examples 1 and 2 describe naked Dsg3 DNA injected into a mouse deficient of Dsg3 (Dsg3<sup>-/-</sup>).

No new matter has been introduced by these amendments.

In the Examiner's opinion, as set forth in the Detailed Action, the application contains claims directed to four patentably distinct inventions as follows:

I. Group I, claims 1-41, drawn to a remedy to be used in gene therapy comprising an immunosuppressive agent and a gene responsible for pemphigus and a method of treating said genetic disease;

II. Group II, claims 1-41, drawn to a remedy to be used in gene therapy comprising an immunosuppressive agent and a gene responsible for recessive genetic epidermolysis bullosa hereditaria dystrophica and a method of treating said genetic disease;

III. Group III, claims 1-41, drawn to a remedy to be used in gene therapy comprising an immunosuppressive agent and a gene responsible for junctional epidermolysis hereditaria bullosa and a method of treating said genetic disease; and

IV. Group IV, claims 1-41, drawn to a remedy to be used in gene therapy comprising an immunosuppressive agent and a gene responsible for hemidesmosome epidermolysis bullosa hereditaria or ichthyosis congenita and a method of treating said genetic disease.

In response to the Official Action dated April 4, 2006, in which pending claims 1-41 were subjected to an election, applicants provisionally elect to prosecute the process claims of **Group II (claims 1-41)**. Applicants respectfully disagree with the restriction requirement imposed by the Examiner and the characterizations made of the claimed invention. Accordingly, as is set forth in detail below, this election is made with traverse.

It is the Examiner's position that restriction is appropriate because the groups contain claims that are independent or distinct. Applicants respectfully disagree with the Examiner's position. Applicants respectfully submit that the Requirement for Restriction is improper for at least the reasons stated, and request that the Restriction Requirement be withdrawn and all presented claims be examined on the merits.

At page 800-48, left column, first full paragraph under §808.01 of the MPEP, states that a requirement for an election of species should be made "[i]n all applications in which no species claims are present and a generic claim recites such a multiplicity of species that an unduly extensive and burdensome search is required." Claims 1-4 and 8 are directed to any genetic diseases the invention. Applicants assert that the Restriction Requirement is improper in that all four groups are directed to a method of treating a disease as claimed in Claim 9. The Restriction Requirement should rather be a species election requirement to an individual species of disease of Groups I-IV. In order to comply with the Restriction Requirement, Applicants have deleted the non-elected "species" diseases, *i.e.*, "pemphigus", "junctional epidermolysis hereditaria bullosa", "hemidesmosome epidermolysis bullosa hereditaria", and "ichthyosis congenital". Although Applicants believe that the restriction is improper and should rather be a species election, the Applicants provisionally elect Group II directed to a remedy to be used in gene therapy comprising an immunosuppressive agent and a gene responsible for recessive genetic epidermolysis bullosa hereditaria dystrophica in order to comply with the Restriction requirement. The election is made with traverse. Reconsideration and withdrawal of the restriction requirement are respectfully requested.

Applicants respectfully remind the Examiner that the election of species for prosecution on the merits only applies if no generic claim is finally held to be allowable. In other words, upon examination of the elected species and allowance of a generic claim, applicants are entitled to consideration of claims to additional species which otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. §1.141.

Should the Examiner's search of the provisionally elected "species" be unsuccessful in finding prior art, then applicants respectfully request the Examiner continue searching the non-elected species. Applicants respectfully disagree with the election requirement imposed by the Examiner and the characterizations made of the claimed invention. Accordingly, this election is made with traverse. More specifically, the Applicants respectfully submit that (1) the Applicants are entitled to a reasonable number of species disclosed in an application in accordance with 37 C.F.R. §1.146; and (2) there would be no undue burden on the Examiner to conduct a substantive examination of the claims as related to the embodiments disclosed in the instant application. Therefore, the Applicants respectfully request that the election requirement be withdrawn.

According to M.P.E.P. §803, there are two criteria for a proper requirement for restriction between patentably distinct inventions:

- (1) The inventions must be independent or distinct as claimed; **and**
- (2) There must be serious burden on the Examiner if restriction is not required.

Applicants respectfully submit that (1) all groups of restricted claims are properly presented in the same application; (2) undue diverse searching would not be required; and (3) all claims should be examined together.

The Examiner has not shown that examination of all the pending claims would require undue searching and/or place a serious burden on the Examiner, which is a requisite showing for proper issuance of a restriction requirement. In fact, applicants submit that to

properly search any one group, the other groups must be considered as well to perform a comprehensive search.

With respect to Groups I - IV, all four groups are directed to a remedy to be used in gene therapy comprising an immunosuppressive agent and a gene correcting a deidresponsible for a disease. To search prior art directed to the same invention cannot be deemed "undue diverse searching." Accordingly, the applicants respectfully traverse the requirement for restriction at least on the grounds that examining the identified groups would not be unduly burdensome. So at a minimum, these four groups should be examined together.

In view of the foregoing, the Applicants respectfully submit that claims 1-41 as listed herein are properly presented in this application and that the claims are allowable over the art prior art.

The Restriction Requirement dated April 4, 2006 further states that "[t]he technical feature linking Group I-IV is a composition for gene therapy directed towards a genetic disorder comprising an immunosuppressive agent and a gene responsible for the genetic disease. Fang, et al (Human Gene therapy, 1995, 6 (8), 1039-1044) teach co administration of immunosuppressive agent cyclosporine A and blood clotting factor IX expressing adenoviral for the treatment of hemophilia B" (emphasis added). However, in order to further and expedite prosecution of the instant application, Applicants have amended the claims to administration of a gene in naked DNA or in a liposome subsumption form, *i.e.*, not in a viral vector form.

### **CONCLUSION**

Based on the foregoing amendments and remarks, Applicants respectfully request reconsideration and withdrawal of the election requirement of claims and allowance of this application.

**AUTHORIZATION**

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. **13-4500**, Order No. 4439-4026.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. **13-4500**, Order No. 4439-4026.

Respectfully submitted,  
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